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|--|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/520,621   | 08/24/2005  | Thomas Rueckle       | 263675US0PCT        | 2551             |
| 22850  | 7590        | 01/29/2010           |                     |                  |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| KOSACK, JOSEPH R   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1626   |             |                      |                     |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                     |                  |
| 01/29/2010   |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com

oblonpat@oblon.com

jgardner@oblon.com

### Office Action Summary

**Application No.**

10/520,621

**Applicant(s)**

RUECKLE ET AL.

**Examiner**

Joseph R. Kosack

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 6-16, 19-28 and 35-37 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10-15, 20-23 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 8, 9, 16, 35 and 37 is/are rejected.
- 7) ☒ Claim(s) 19 and 24-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1, 6-16, 19-28, and 35-37 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 30, 2009 has been entered.

#### ***Previous Claim Objections***

Claims 1, 2, 4-6, 8, 9, 17-19, 24-29, 31, 32, 35, and 37 were previously objected to for containing elected and non-elected subject matter. The elected species is now found to be patentable. However, as a rejection can be made on a subsequent species, the objection is maintained except for those claims cancelled by the Applicant.

#### ***Previous Claim Rejections - 35 USC § 112***

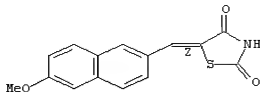
Claims 1, 2, 4-6, 8, 9, 17, 18, 28, 29, 31, and 32 were previously rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of inflammation, does not reasonably provide enablement for treatment of any other disease.

The Applicant has deleted the non-enabled subject matter, and the rejection is withdrawn.

#### ***Expansion of Search***

As the elected species has been found to be patentable, the search has been

expanded to encompass the species



### ***Claim Objections***

Claims 1, 2, 6, 8, 9, 16, 19, 24-28, 35, and 37 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra. Applicant is advised that additional subject matter may be searched after all rejections are removed from the elected species.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 8, 9, 16, 35, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a composition and methods of using a composition of compounds of formula I or pharmaceutically active derivatives thereof. The definition for a pharmaceutically active derivative, as stated on page 16 of the instant specification, "refers to any compound that upon administration to the recipient, is capable of providing directly or indirectly, the activity disclosed herein." However, there is no description as to what the structure of these pharmaceutically active derivatives would be. Therefore, the person of skill in the art would be unable to determine the

metes and bounds of the claim. It is recommended that the term "pharmaceutically active derivatives thereof" be deleted from the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

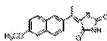
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 8, 9, 16, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prabhakar et al. (*Bioorganic & Medicinal Chemistry Letters*, 1998, 2725-2730).

Prabhakar et al. teach a compound for the treatment of inflammation and a



composition of the compound of the formula . See compound 14, page 2727 and test results for treating inflammation on page 2729. This corresponds to the claims where A is a carbocyclic ring, n is 0, R<sub>2</sub> is C1 alkoxy, R<sub>1</sub> is hydrogen, X is S, Y<sub>1</sub> and Y<sub>2</sub> are O, and a methyl group is attached to the central alkene group.

Prabhakar et al. do not teach where the methyl group on the central alkene group is replaced by a hydrogen atom.

Hydrogen and methyl are obvious variants as in the pharmaceutical art. The court in In re Wood, Whittaker, Stirling, and Ohta (199 USPQ 137) state that compounds with similar structures are expected to have similar properties unless there is evidence on the record of secondary considerations, and specifically referenced hydrogen vs. methyl substitutions. Therein lies the motivation and a reasonable expectation of success. As the disclosure does not contain any unexpected results of the presently claimed compounds, they are deemed to be obvious variants over the compounds of Prabhakar et al.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

### **Conclusion**

Claims 1, 6, 8, 9, 16, 35, and 37 are rejected to. Claims 1, 2, 6, 8, 9, 16, 19, 24-28, 35, and 37 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/  
Examiner, Art Unit 1626

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